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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 041404

Application Number: 09/448,420
Filing Date: November 22, 1999
Appellant(s): SEUL ET AL.

Eric P. Mirabel
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on 1/15/04.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

Upon further consideration claims 169-174 are no longer rejected, and are now objected to as dependent on rejected claims.

Claims 1-128 have been canceled.

Claims 129-174 are pending.

Claims 152, 153 and 167 have been withdrawn from consideration.

Claims 129-151, 154-166 and 168 have been rejected.

Claims 169-174 are objected.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because claims 169-174 are now objected.

It is noted Appellants has grouped claims 173-174 as patentably distinct from other claims, however in the arguments section D) refers to claims 172-174 as separate invention.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,728,529 METZEKER et al 05-1998

WO 93/06121. Dower et al 01/04/1993.

Boyce et al. J. Am. Chem. Soc., Vol. 116, No. 17, 1994.

(10) Grounds of Rejection

NOTE that the rejections of claims 169-174 applied in the previous rejections have been withdrawn and the claims are now objected as dependent on rejected claims.

The following ground(s) of rejection are applicable to the appealed claims:

A). Claims 129-151, 160-166, 168 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce et al (J. Am. Chem. Soc., Vol. 116, No. 17, 1994).

The instant claims briefly recite a method of identifying a compound of interest in a library of compounds, each of said compounds being bound to a solid support, and prepared by split synthesis, adding one or more tags to the solid support; and decoding the code composed of one or more tags; performing an assay capable of indicating that any compound in the library has a property of interest; decoding the code composed of one or more tags to identify the compound, wherein the decoding step is carried out without isolating the solid support comprising the compound from other solid support and without detaching the tag from the solid support, and wherein the decoding step comprises *in situ* optical interrogation of the tag.

Boyce et al disclose peptido steroidal receptors for opoid peptides. The reference discloses split synthesis using polystyrene beads. The reference discloses that the combinatorial synthesis led to 10^2 variants of V1 and was encoded with eight molecular tags using a binary tagging method. Finally encoded split synthesis was employed with eight more tags to complete V2. This double split synthesis led to a 10^4 member library in which each different member of the library was attached to a different synthesis bead (refers to steps a)-e) of the instant claims). The reference discloses to test the library for receptor substrate binding. The binding screen was conducted as a solid phase assay in which a sample of the beads were treated with a dilute solution of substrate tethered to an intensely colored dye. The dye-linked receptor library was then screened for binding with encephalon (refers to the instant claim step f)). The reference discloses that many beads had developed light orange coloration and few turned bright red (refers to said decoding step comprises in-situ optical interrogation of the instant claims). The reference discloses that bright red beads (refers to other solid supports) and decoded their synthetic history . Thus, the reference clearly anticipates the claimed invention.

B). Claims 129-138, 142-146, 151, 154 and 159-166, 168 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/06121 (Dower et al).

Dower et al disclose a general stochastic method for synthesizing random oligomers, which can be used to synthesize compounds to screen for desired properties. The reference discloses that the use of the identification tags on the oligomers facilitate identification of

oligomers with desired properties (see the abstract). The reference discloses that the random oligomers are synthesized on solid supports, or particles, but may be cleaved from these supports to provide a soluble library. The oligomers are composed of a sequence of monomers, and the library is screened to isolate individual oligomers that bind to a receptor, or possess a desired property (see page 4). The reference discloses that an identifier tag is used to identify the sequence of monomers in the oligomer. The reference discloses that the identifier tag is directly attached to the oligomer with or without an accompanying particle, to the solid support upon which the oligomer is synthesized (see page 4). The reference discloses that the identifier tag may be composed of a set of light addressable compounds, such as fluorescent or phosphorescent compounds, which are incorporated into the beads or particles on which the oligomers of the oligomer library are synthesized. The reference discloses that the coded identifier tags may be used to so that each monomer is assigned a specific binary number (i.e., see page 26, lines 3-4) (refers to bits of binary code of the instant claims). The reference discloses such compounds are well known in the art (i.e., see last paragraph in page 4 bridging page 5). The reference discloses a method for producing tagged synthetic oligomer libraries (i.e., see pages 15-19). The reference discloses split-pool synthesis of the oligomer library (i.e., see page 16). The reference discloses the method for identification of the sequence of the oligomer (i.e., page 19). The reference discloses that the tags may be attached immediately before, during , or after the monomer addition, as convenient as compatible with the type of identifier tag, modes of attachment and chemistry of oligomer synthesis. The identifier tag is added when the solid support that have undergone a specific monomer addition step are physically together so can be

tagged as a group. The reference discloses that the fluorescent beads are recovered from the positive wells . The beads are removed and sorted by FACS. The reference discloses that the compounds of the library are identified using a competitive assay, in which diminished fluorescence caused by the oligomer library competing with the ligand are identified (i.e., see page 31). The reference clearly anticipates the claimed invention.

C). Claims 129-138, 142-146, 151, 155-166, 168 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,968,736 (Still et al) .

Still et al discloses methods for recording the reaction history of a solid support. The reference discloses encoded combinatorial chemistry, in which sequential synthetic schemes are recorded using organic molecules, which define choice of reactant, and stage, as the same or different bit of information. The reference discloses that various products can be produced in multistage synthesis, such as oligomers and synthetic non-repetitive organic molecules (see abstract). The reference discloses that nested families of compounds can be employed as identifiers, where the number and/or position of a substituent define the choice, and alternatively detectable functionalities such as radioisotopes, fluorescers, halogens can be used (see abstract). The reference discloses that the invention provides methods and compositions for encoded combinatorial synthesis whereby at each stage of the synthesis one or more identifiers are provided, which encode and event associated with a particle stage in the synthesis of the compound on the support (i.e., see column 7, lines 1-4). The reference discloses that the N identifiers, and M distinguishable states are provided (see column 7, lines 14-15); and in case if

M is 2 where the two states could be the presence of absence of identifier, the synthesis thus defined by a base 2 or binary code (i.e., see column 7, lines 15-18) (refers to the fluorophore tag represents a bit of binary code of the instant claims). The reference discloses that the synthesis of oligomers on solid support begin with a number of beads, which would be divided into groups, and then add the reagents and the identifiers which encode the reagent and the stage of the reaction. And after the synthesis is completed, the compounds are screed for desired property either after detachment of the ligand (compound) from the bead or **while still attached** (i.e., see column 17, lines 4-6). The reference discloses that the beads with ligand attached are incubated in aqueous buffer with monoclonal antibody (for the property to be tested), and the fluorescent beads with attached monoclonal antibody are identified and separated by manually or using FACS from the unstained beads, so long as the tags are retained on the bead under the conditions of sorting. The reference teaches that the fluorescent beads with attached compound are identified from the unstained beads, thus, the reference analyzed the fluorescent data of the beads, to identify the compound of interest in the library. Thus, the reference clearly anticipates the claimed invention.

D). Claims 129-151, 154-166, 168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower (WO 93/06121) in view of Metzeker et al (US patent 5,728,529).

Dower et al have been discussed supra.

The claimed invention differs from the prior art teachings by reciting that the fluorescent tags of specific chemical structures. Dower et al teach methods of synthesizing diverse

collections of oligomers. Dower et al teach the use of identifier tags. Dower et al fail to teach the fluorescent tags of the specific structures of the claims 139-141. However, Metzeker et al teach alternative dye-labeled RNA, DNA for DNA analysis. The reference teaches a new class of dyes, which have improved spectral characteristics and improved stability. The reference teaches that because of the improved properties of these dyes, they are useful in any method of detection of DNA, and the spectral properties of the fluorophores are similar in wavelength and intensity to be used with conventional equipment known in the art. Thus, it would have been obvious to a person skilled in the art at the time the invention was made to use the fluorescent dyes taught by Metzeker et al in the method of oligomer library synthesis and identification of the compounds of interest using identifier tags taught by Dower et al, because Metzeker et al teach novel class of fluorescent dyes which can be useful to label the DNA, RNA, and has improved spectral properties, and can be use din any assay method, and Dower et al teach a method of using identifier tags (fluorescent or oligonucleotide) to label the solid supports to which an oligomer of a oligomer library is attached. A person skilled in the art at the time the invention was made to use the fluorescent dyes taught by Metzeker et al in the method of combinatorial library of compound synthesis with the expectation of identifying the compound of interest using conventional equipment known in the art.

(11) Response to Argument

A). Claims 129-151, 160-166, 168 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce et al (J. Am. Chem. Soc., Vol. 116, No. 17, 1994).

Discussion

Appellants argue that Boyce et al teach two-step process, parallel to steps (f) and (g) of claim 129. Appellants argue that in Boyce et al reference use 'in-situ optical interrogation' to determine which beads turned bright red, and determining positive beads is related to the assay step (f) of the instant claim and is not part of 'decoding .... To identify the compounds' in step g) of the instant claims.

Appellants arguments have been fully considered and are not persuasive, since Boyce et al teach that the dye-linked receptor library was then screened for binding with encephalon (refers to the instant claim step f)); and Boyce et al teach 'binding was detected by simple inspection, the library beads bound to the substrate picked up the colored dyes (or turned red) (refers to the instant claim step g)). Thus, Boyce et al teaches both steps f) and g) of the instant claims.

Appellants arguments that the reference teaches *in-situ* optical interrogation of which beads turned bright red is related to assay step f) has been fully considered and is not persuasive. Since the reference Boyce et al clearly teach the assay step f) (assaying for binding with the encephalon) and further teach that the optical interrogation of the positive beads (beads which

bound to encephalon), which clearly reads on the instant claim step g) (decoding to identify the compound associated with the code).

And appellants argue that the reference decoding step does not include 'in-situ optical interrogation of the tags.' Appellant's arguments have been considered and are not persuasive, because the reference method clearly teaches the positive beads (bright red) with the compound of interest have been identified by visual inspection (in-situ optical interrogation). The reference method may have additional decoding steps using gas chromatography, which is not relevant to the instant claimed method steps, and further the instant claimed method is open ended by reciting 'comprising' which may include further method steps. Appellant's arguments regarding the use of gas chromatography by the reference is not relevant to the instant claimed invention Since, the reference identifies the positive beads or the beads with the compounds of interest by visual inspection which reads on the 'decoding the code composed of one or more tags to identify the compound associated with the code....wherein said decoding step comprises in-situ optical interrogation'of the instant claimed method.

Appellants argue that Boyce et al do not disclose any of the following elements of claim 129, step g): 'decoding the code composed of one or more tags to identify the compound associated with the code, wherein the decoding step is carried out (i) without isolating the solid support of interest from other solid supports and (ii) without detaching any of the tag from the solid support of interest and wherein (iii) the decoding step comprises in-situ optical interrogation of the tags.'

Appellant's arguments regarding claim 129 step (g), how the decoding of the tag is carried out has been fully considered and is not persuasive. Boyce et al clearly teach the method of decoding steps of the instant claims. Boyce et al teach identification or detection (refers to the instant claim decoding) of the binding of the receptor library to the enkephalin by simple inspection. The reference teaches after agitation of the mixture, that many beads has developed light orange coloration, but that only a few had turned bright red, which refers to the step decoding without isolating the solid support from other solid supports (light orange beads and red beads in the mixture of the reference); and detecting the bright red beads in the mixture refers to the instant claim decoding (ii), 'without detecting the tag from the solid support'; and detecting the bright red beads in the mixture again refers to the instant claim decoding step (iii) *in-situ* optical interrogation of the tags. Thus, the reference clearly teaches all the limitations of the claimed invention.

B). Claims 129-138, 142-146, 151, 154 and 159-166, 168 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/06121 (Dower et al).

Discussion

Appellants argue that Dower et al discusses , a process of synthesizing a solid support-based combinatorial library, a two step process of (i) screening to isolate compounds with a desired property, and (ii) decoding an identifier tag to identify a compound on a particular support.

Appellants assert that the term 'in-situ optical interrogation' only appears in step (g) of claim 129, which is the step where one is 'decoding the code composed of one or more tags to identify the compound associated with the code... and wherein said decoding comprises in-situ optical interrogation of the tag.' Appellants further argue that 'selecting positive beads by visual inspection in Dower et al does not refer to the "decoding the code composed of the tag to identify the compound..', and ...'selecting the beads' refers to step (f) of claim 129, and 'decoding to identify the compound ....optical interrogation' is the language from step (g) of claim 129.

Appellants assertions and arguments regarding the instant claim 129 steps f) and g) and difference of these steps compared to Dower et al have been considered and are not persuasive. Appellant's interpretation of Dower et al teaching of only step (f) of the instant claims and not step (g) is improper. Dower et al clearly teach 'after the receptor assay (the receptor assay refers to the instant claim step (f)), the positive beads (identify the compound of interest) are identified and isolated using fluorescent activated solid support sorting (which refers to the instant claim decoding the tag to identify the compound, wherein decoding comprises optical interrogation). Thus, Dower et al teach steps (f) and (g) of the instant claims.

Appellants further argue that Dower teaches that the light addressable fluorescent beads are isolated prior to the tag identification. This is contrary to the claimed invention, which provided in situ optical interrogation of beads without isolation from other beads in the array. Appellants argue that Dower et al has not elaborated specific methods for decoding the codes are not described, and the decoding steps described in Dower et al all involve isolation of the beads

to be decoded, leading to the conclusion that these light addressable tags are also to be decoded in this same manner...'

Appellants response regarding the 'fluorescent tags' of the reference have been considered, however are not persuasive, since in Dower et al decoding refers to identify the sequence of the compound, which is different from 'identifying the positive compound (i.e., the compound which has the preferred property).' However, the instant claims only recite that 'in-situ optical interrogation to identify the compound' and the limitation 'to determine the structure or sequence of the compound attached to the bead' is not part of the instant claim.

In response to appellant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., determining the sequence or the structure of the compound attached to the bead by *in-situ* optical Interrogation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Appellants further argue that in claim 129 step © recites that the 'code is uniquely associated with a compound and a corresponding reaction sequence is determined by optical interrogation. Thus, the 'sequence or structure' of the compound will be determined by performing the decoding step (g), which determines the reaction sequence from which the sequence or structure naturally flows.'

Appellant's assertions have been considered and are not persuasive because, the instant claim step (g) recites 'decoding to identify the compound associated with the code' which refers

to identification of positive bead with the compound attached to the bead. In the instant claim step © recites the property of the code (i.e., capable of determining reaction sequence by optical interrogation) used in the claimed method, however the method steps, especially step g) does not recite that the reaction sequence or the structure or sequence of the compound attached to the bead is identified by in-situ optical interrogation . Dower et al further teach that the 'identifier tag' provides a means whereby one can identify which monomer reactions an individual solid support has experienced in the synthesis of oligomer and the identifier tag records the steps in synthesis series. Dower et al teach that the identifier tag is any recognizable feature, including microscopically distinguishable shape or size, color, optical density etc, or differently absorbing or emitting light (refers to the instant claim 'code' which is identified by the optical interrogation) (i.e., see page 10, under types of identifier tags), thus Dower et al clearly teach the use of identifier tags to determine the structure or sequence of the compound or the sequence of the reaction series the solid support has undergone. Thus, the reference clearly anticipates the claimed invention.

C). Claims 129-138, 142-146, 151, 155-168 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,968,736 (Still et al) .

Discussion

Appellants argue that Still does not anticipate Applicants' invention, because nowhere does Still teach or suggest tag decoding **without isolating the solid support of interest from**

other solid supports. In fact, Still requires separation of beads containing attached fluorescent-Mab by means of FACS.

Appellants arguments have been considered and are not persuasive because Still et al teach that families of compounds can be employed as identifiers, where the number and/or position of a substituent define the choice, and alternatively detectable functionalities such as radioisotopes, fluorescers, halogens can be used. And the reference teaches after synthesis is completed, the reaction products are screened for desired property by incubating the beads with fluorescently labeled Antibody and the positive beads are identified and separated, which refers to the in-situ optical interrogation of the beads to identify the compound with desired biological property of the instant claims. Appellants argue that Still et al does not teach decoding without isolating the solid support. This is not persuasive, since the teaching s of Still et al identification of positive beads with fluorescent tag (refers to the instant tag) from among the other beads, refers to decoding to identify the compound, ...wherein said decoding step comprises in-situ optical interrogation of the tag, of the instant claims.

Appellants further assert that claim 129 step © recites that the 'code is uniquely associated with a compound and a corresponding reaction sequence is determined by optical interrogation. Thus, the 'sequence or structure' of the compound will be determined by performing the decoding step (g), which determines the reaction sequence from which the sequence or structure naturally flows.' Appellant's assertions have been considered and are not persuasive because, the instant claim step (g) recites 'decoding to identify the compound

associated with the code' which refers to identification of positive bead with the compound attached to the bead. In the instant claim step © recites the property of the code (i.e., capable of determining reaction sequence by optical interrogation) used in the claimed method, however the method steps, especially step g) does not recite that the reaction sequence or the structure or sequence of the compound attached to the bead is identified by in-situ optical interrogation .

Appellants further argue that Still et al teaches away from the feature of the claimed invention, wherein the decoding takes place without detaching any of the tag from the solid support.

Appellant's arguments have been considered and are not persuasive, since Still et al teach after the synthesis is completed, the compounds are screed for desired property either after detachment of the ligand (compound) from the bead or **while still attached**, which clearly anticipates the claimed invention. And the reference teaches after synthesis is completed, the reaction products are screened for desired property by incubating the beads and the positive beads are identified which refers to the in-situ optical interrogation of the beads to identify the compound with desired biological property of the instant claims. Thus the reference clearly anticipates the claimed invention.

D). Claims 129-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower (WO 93/06121) in view of Metzeker et al (US patent 5,728,529).

Discussion

Appellants argue that Metzker fails to remedy the deficiencies of Dower et al, Metzker fails to teach or suggest a method of identifying compounds of interest in a library of compounds bound to solid supports wherein an optically distinguishable tag on a solid support of interest is interrogated in *situ*.

Appellants arguments have been considered and are not persuasive, since Metzker et al teach the fluorescent dyes used in the instant claimed method, and Dower et al teach a method of synthesis and screening of a library of compounds attached to beads, and the beads are labeled with fluorescent tags. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 U. S. P. Q. 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 U. S. P. Q. 375 (Fed. Cir. 1986). From the combined teachings of Dower et al and Metzker, it would have been obvious to one skilled in the art at the time the invention was made to synthesize a combinatorial library of compounds attached to beads and identify the positive compounds still attached to the bead from among other beads.

Appellants argue that Metzeker only describe the use of the modified versions of a new class of dyes, i.e., BODIOY.RTM. fluorophores, for DNA sequencing by the chain termination method of DNA sequencing. Metzeker et al do not in any way suggest or motivate on e to make the claimed invention, as these dyes and methods are not used for 'decoding the code composed of one or more tags to identify the compound of the instant claim 129.

Appellant's arguments regarding Metzeker et al have been fully considered and are not persuasive. Appellants argument that the dyes taught by Metzeker et al are not used for decoding the code composed of tag to identify the compound and only allows determination of classes of polynucleotides, is not persuasive, because Metzeker et al the teach that the dyes are useful in any method of detection of DNA (refers to instant claim compound) and the spectral properties of the fluorophores are similar in wavelength and intensity to be used with conventional known equipment known in the art. Thus, it would have been obvious to one skilled in the art at the time the invention was filed to use the fluorescent dyes taught by Metzeker et al in the method of detection of compounds from a library taught by Dower et al.

Further appellants argue that Metzeker et al method only allows determination of classes of polynucleotides (not "decoding ....to identify the [polynucleotides]" as in claim 129 which have same 3'terminal dideoxynucleotides, or classes which contain the same deoxynucleotides.

Appellants arguments regarding "Metzeker et al method is useful only to detect the same class of compounds, i.e., polynucleotides with same 3' terminal dideoxynucleotides or classes which contain deoxynucleotides' are not persuasive, since the instant claimed method is drawn to identifying compounds (broad genus of compounds which may include polynucleotides), and the compounds do not exclude different classes of polynucleotides.

And further appellants assert that the instant claim 129 is drawn to "decoding ....to identify the [polynucleotides]." Appellants arguments/assertions that the references fail to show certain features of the instant claim 129 (i.e., identifying polynucleotides), it is noted that the features upon which appellants relies (i.e., identification of polynucleotides) are not recited in the

rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Appellants argue that although fluorescent tags are mentioned in Dower et al, their decoding is not described. Appellants arguments have been considered and are not persuasive, since Dower et al teach that the identifier tags provides a means whereby one can identify which monomer reactions an individual solid support has experienced in the synthesis of oligomer and the identifier tag records the steps in synthesis series. The reference teaches that the identifier tag is any recognizable feature, including microscopically distinguishable shape or size, color, optical density etc, or differently absorbing or emitting light (refers to the instant claim 'code' which is identified by the optical interrogation).

Appellants argue that Dower do not mention anywhere that with respect to any type of identifier tags discussed the 'decoding step is carried out without isolating the solid support of interest from other solid supports.' Appellants arguments are not persuasive, because Dower et al clearly teach 'after the receptor assay (the receptor assay refers to the instant claim step (f)), the positive beads (identify the compound of interest) are identified and isolated using fluorescent activated solid support sorting , which refers to the instant claim decoding the tag to identify the compound, wherein decoding comprises optical interrogation. Thus the combined teachings of Dower et al and Metzeker clearly read the claimed invention.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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